

REMARKS

The Examiner is thanked for his consideration of this case and for the conditional allowance of Claims 3-6 and 9, providing these claims are amended in independent form to include all limitations of the base claim and any intervening claim. However, after a thorough consideration of the prior art of record applicants are not amending any of the claims, but instead requesting the Examiner to reconsider the rejections for the reasons set forth herein. Claims 1-15 are in the application, Claims 10-15 being directed to a non-elected invention.

Reconsideration is respectfully requested of the rejection of Claims 1, 2, and 8 under 35 U.S.C. 102(b) as anticipated by Sieben, et al. (U.S. 5,820,548).

The present invention relates to an iontophoresis device and a method for detecting a physiological substance which can be used in diagnosis and examination in the medical field. There have not been in the prior art devices and methods of detection where desired substances can be detected rapidly and in high selectivity. This creates a problem that a correct diagnosis in a short period of time cannot be performed for the detection of some types of diseases.

The present inventors unexpectedly discovered that this problem could be solved by use of a member for detection

constituted so as to suitably adsorb a physiological substance in connection with an iontophoresis device. Specifically, in the case of diagnosis of diseases such as tumors, for example, an iontophoresis is performed using a device structure for diagnosis which contains a member for detection having high adsorption of a protein, peptide, nucleotide, etc., which are markers of tumors and the like.

The physiological substance is adsorbed and fixed onto the member for detection by electrical driving power. Then, the member for detection is detached from the device and the tumor-related antigens, tumor markers or tumor-related substances which have been adsorbed and fixed are then measured by immunological or chemical methods.

The iontophoresis device of the present invention comprises an electrode for iontophoresis, a member for detection constituted so as to adsorb a physiological substance by the iontophoresis, and a conductive layer arranged between the electrode and the member for detection. Preferably the member for detection is composed of a porous membrane and preferably has an adsorbability of proteins to the member for detection of 20 $\mu$ g per square centimeter.

The Sieben, et al. reference relied upon by the Examiner relates to an apparatus for treating malignant tissue changes and

comprises a sensor-actuator head having at least one sensor for measuring acidity values of an environment adjacent to malignant tissue cells, and at least one dispensing devices for providing an active ingredient for chemical action and treatment electrodes for effecting a physiological action through electric and/or electromagnetic fields being provided on the sensor-actuator head for application to an area of the malignant tissue to be treated. Thus, it can be seen, that Sieben, et al. are concerned with delivering a chemical substance to the area of a tumor rather than the present invention which is concerned with obtaining from the body proteins, peptides, nucleotides, etc. (markers of tumors) which can then be measured by immunological or chemical methods.

It is respectfully submitted that there is no disclosure whatever in Sieben, et al. of either a "member for detection constituted so as to adsorb a physiological substance by iontophoresis", or a "conductive layer arranged between said electrode and the member for detection". On the contrary, that teaching or suggestion comes only from the present application and constitutes an important element or aspect of the present invention.

According to Sieben, et al., there is provided "for monitoring the treatment area, at least one sensor is provided

for determining the acidity in the treatment area, since changes in the pH value permit inferences about the metabolic activities of the tumor cells. Appropriate treatment adaptations can thereby be undertaken" (col. 1, lines 45-49 of Sieben, et al.).

It is therefore clear that Sieben, et al. essentially intends to measure pH using a pH sensor and makes the measured value reflected in the medical treatment. However, Sieben, et al. does not provide a member for detection constituted so as to adsorb a physiological substance by iontophoresis as called for in the claims herein. Further, there is no disclosure in Sieben, et al. of a conductive layer arranged between the electrode and the member for detection. Therefore, the effect of the present invention such that the desired substances etc. can be detected rapidly and in high sensitivity (see page 6, lines 8-9 of the present application) cannot be obtained using the device disclosed by Sieben, et al. Therefore, the device of Sieben, et al. does not inherently disclose the same effects as the apparatus of the present invention.

Since the Sieben, et al. reference fails to disclose the essential elements of the iontophoresis device called for in Claims 1, 2 and 8 herein, it is respectfully submitted that Sieben, et al. neither anticipates nor renders unpatentably obvious the subject matter called for in these claims.

In relying upon the theory of inherency, the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristics naturally flow from the teachings of the prior art. Ex parte Levy, 17 USPQ 2d 1461 (BPAI 1990). There must be no difference between the claimed invention and the disclosure, as viewed by a person of ordinary skill in the field of the invention. Scripps Clinic & Res. Found. V. Genentech Inc., 18 USPQ 2d 1001 (CAFC 1991).

In the present case, the Examiner has not provided a basis in fact or technical reasoning to reasonably support the determination that the apparatus of Sieben, et al. inherently functions in the same way as the apparatus called for in the claims herein. It is respectfully submitted that there are major differences between the device disclosed by Sieben, et al. and the present invention.

In Sieben, et al. the disclosed device is administering a compound to the treatment area while the iontophoresis device of the present invention contains a member for detection constituted to adsorb a physiological substance from the body. These fundamentally different processes and structures would not, it is submitted, be considered by one of ordinary skill in the art to even be the same types of devices. For these reasons, it is

respectfully submitted that the rejection fails, as a matter of law, in view of the above authorities. Consequently, the Examiner would be justified in no longer maintaining the rejection.

Reconsideration is respectfully requested of the rejection of Claim 7 under 35 U.S.C. 103(a) as being unpatentable over Sieben, et al. in view of Sage, et al., (U.S. 5,961,483).

The Sieben, et al. reference is discussed above.

The Examiner's secondary reference of Sage, et al. fails to cure the deficiencies of the Sieben, et al. reference since there is no disclosure whatever in Sage, et al. of a iontophoresis device comprising an electrode for an iontophoresis, a member for detection constituted so as to adsorb a physiological substance by the iontophoresis, and a conductive layer arranged between said electrode and said member for detection. Moreover, there is no disclosure in Sage, et al. of an iontophoresis device having a member for detection constituted so as to adsorb peptides or proteins secreted from one of living tissues, blood and cells. On the contrary, that teaching or suggestion comes only from the present application and constitutes important element or aspect of the present invention.

The Sage, et al. reference is concerned with an iontophoresis device for administering therapeutic doses of cell adhesion receptor antagonists in a controlled manner through the

skin. It is therefore clear that neither the Sage, et al. nor the Sieben, et al. reference disclose an iontophoresis device having a member for detection which adsorbs a physiological substance by iontophoresis, and a conductive layer arranged between an electrode and the member for detection.

Therefore, it is respectfully submitted that combining these references in the manner suggested by the Examiner would not yield the structure or process of the present invention. Consequently, the Examiner's combination of references neither anticipates nor renders unpatentably obvious the subject matter called for in Claim 7. Withdrawal of the rejection is accordingly respectfully requested.

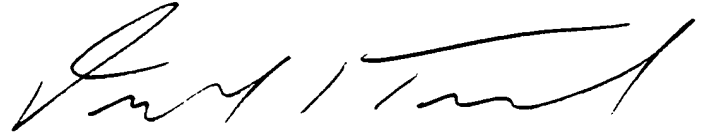
Regarding claims 3-6 and 9, it is respectfully submitted that the prior art of record fails to disclose the subject matter of these claims for the reasons discussed above. Consequently, these claims should be allowed over the prior art of record for these reasons.

In view of the foregoing, it is respectfully submitted that the application is now in condition for allowance, and early action and allowance thereof is accordingly respectfully requested. In the event there is any reason why the application cannot be allowed at the present time, it is respectfully requested that the Examiner contact the undersigned at the number

listed below to resolve any problems.

Respectfully submitted,

TOWNSEND & BANTA



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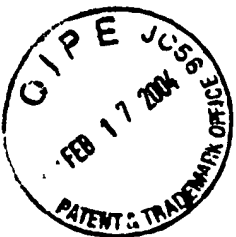


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